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| 09/991,417 | 11/16/2001 | Juan Carlos Parodi | AMS-2CIP CON | 4044 |

7590 07/30/2003

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EXAMINER

SIRMONS, KEVIN C

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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3763

DATE MAILED: 07/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/991,417

Applicant(s)

PARODI, JUAN CARLOS *On*

Examiner

Kevin C. Sirmons

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5,6,8-15 and 18-20 is/are pending in the application.
- 4a) Of the above claim(s) 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,6,8-10,12-15 and 18-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
- 2) ☒ Certified copies of the priority documents have been received in Application No. 09/418,727
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

Applicant's election of Species I Fig. 3A-3D in Paper No. 9 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicant has elected claims 1-3, 5, 6, 10-15 and 19-20 to be examined.

Claim 11 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Species IV, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valley et al U.S. Pat. No. 5,814,016.

Valley discloses an apparatus for removing emboli from the cerebral, vasculature, the apparatus comprising: a catheter having proximal and distal ends ((10) of Figs. 1 and 29), a lumen extending therethrough (figs. 1 and 29), and a blood outlet port in communication with the lumen (32/33), the catheter having an outer diameter sufficient to permit the catheter to be disposed in the cerebral vasculature (col. 9, lines 4-10 and col. 10, lines 9-14),

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Note: the carotid artery is a part of the cerebral vasculature, therefore, the catheter has an outer diameter sufficient to permit the catheter to be disposed in the cerebral vasculature; the occlusion element having a contracted state suitable for transluminal insertion (the device of Valley is fully capable of the function) and an expanded state wherein the occlusion element occludes antegrade flow in the vessel (The occlusion element is not large enough to occlude the Aorta. However, it is large enough to occlude the carotid artery when the occlusion element is placed in the smaller carotid artery (not shown) and expanded. The occlusion element would then occlude antegrade flow in the artery.), the occlusion element extending beyond the distal end of the catheter in the expanded state to form a tapered entrance to the lumen (fig. 29); a venous return catheter having a proximal end with an inlet port (proximal end of 19) and a distal end with an outlet port (distal end of 19), and a lumen extending therebetween (interior of 19), the blood outlet port (32/33) coupled to the inlet port of the venous return catheter (the blood outlet port 32/33 is indirectly coupled to the inlet port of the venous return catheter (19 and fig. 1) and just as shown in applicant figures).

Valley does not disclose a pear-shaped inflatable occlusion element disposed on the distal end of the catheter (161). Note: The examiner has thoroughly reviewed applicant's specification (specifically page 17, lines 12-26) and has concluded that applicant has provided very little if any structure and/or criticality for a pear shaped balloon. Applicant has indicated that the distal end of the catheter provides an atraumatic tip or bumper for the catheter, which Valley fully discloses (161). As a result, the examiner has given pear-shaped the broadest reasonable interpretation. Therefore, it would have been an obvious matter of design choice to change the shape of the balloon to a pear-shaped balloon (specifically the proximal end of the balloon),

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since such a modification would have involved a mere change in the shape of a component. A change in shape is generally recognized as being within the level of ordinary skill in the art. Although applicant has stated the purpose for the distal part of the balloon, he has not stated the purpose/criticality for the proximal part of the balloon. Furthermore, it would appear that the invention would perform equally well with the balloon (161) as disclosed by Valley. As to claim 3, (37).

Claim Rejections - 35 USC § 103

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Valley et al U.S. Pat. No. 5,814,016 in view of Stevens et al U.S. Pat. No. 5,916,193.

Valley discloses an apparatus for removing emboli from the cerebral vasculature substantially as claimed except for a roller pump although she clearly discloses a pump (18). However, Stevens (193) discloses a roller pump (col. 4, lines 28-43 and fig. 1, (18)) that engages the venous return catheter (19) to assist in drawing blood through the catheter and in reperfusing blood via the venous return catheter (19). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Valley with the roller pump as taught by Stevens to withdraw blood, remove CO. sub. 2 from and add oxygen to the withdrawn blood and then pump the oxygenated blood through the return catheter to the artery (col. 16, lines 26-42).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

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improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3, 5, 6 and 10 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 3, 4 and 6 of U.S. Patent No. U.S. Pat. No. 6,423,032. Although the conflicting claims are not identical, they are not patentably distinct from each other because pending claim 1 simply fails to recite (a wire having a distal end and a balloon disposed on the distal end, wherein the wire and balloon are sized to pass through the lumen of the catheter from patented claim 1). This is a mere broadening of the patented claims See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993).

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.


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Claims 2/1, 8/1, 12, 13, 14, 15, 19 and 20 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 8, 15, 16, 17, 19, 21 and 20 of prior U.S. Patent No.

Parodi U.S. Pat. No.6,423,032. This is a double patenting rejection.

Conclusion

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Kevin C. Sirmons whose telephone number is (703) 306-5410. The examiner can normally be reached on Monday - Thursday from 6:30 am to 4:00 pm. The examiner can also be reached on alternate Fridays.


Kevin C. Sirmons
Patent Examiner
7/25/03

